

REMARKS

An Office Action was mailed in the above-captioned application on November 26, 2007. Claims 1-12 were pending in the application. Claims 1-12 were rejected. This Amendment and Remarks document is submitted in response to said Office Action.

The Rejection under 35 U.S.C. § 112, second paragraph

The Examiner has rejected Claims 1, 3-6, 8, 9, 11, and 12 under 35 U.S.C. § 112, second paragraph. The second paragraph of Section 112 requires that the claims set out and circumscribe a particular area that applicants regard as their invention with a *reasonable* degree of precision and particularity.

Specifically, the Office action states that the term “hot” in claim 1 is a relative term which renders the claim indefinite. Claim 1 has been amended to delete the word “hot” and to incorporate the limitation of Claim 2 into claim 1. Claim 1 now recites extracting *Nelumbinis Semen* with water at 80-100°C for 1-3 hours. In view of this amendment, claims 7 and 10 have been amended to depend from claim 1.

It is believed the amendment overcomes the rejection under 35 U.S.C. § 112, second paragraph and reconsideration and withdrawal of the rejection is respectfully requested.

The Rejection under 35 U.S.C. § 102(b)

The Examiner has rejected Claims 1-2, 5-7, and 10 under 35 U.S.C. § 102(b) as being anticipated by Kim, et al., WO 02/102397 (US 2004/0185128 A1 as translation). The Court of Appeals for the Federal Circuit has stated that anticipation requires the presence in a single prior art reference of each and every element of the claimed invention. *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984); *Alco Standard Corp. v. Tennessee Valley Auth.*, 1 U.S.P.Q.2d 1337, 1341 (Fed. Cir. 1986). "There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic v. Genentech Inc.*, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991) (citations omitted). As explained in detail below, Applicant believes that claim 1, as amended, is not anticipated by the prior art relied upon.

Specifically, the rejection alleges that Kim, et al., teaches a herb selected from *Nelumbinis Semen* in Claim 8, that the extract is a water extract in Claim 12, extracting at 80-100 degrees for 1 to 24 hours and filtering the extract in Claim 13, and as a pharmaceutical

composition in Claim 14. The rejection also alleges that Kim, et al., teaches a powder form of the extract prepared by removing the solvent under reduced pressure in paragraph [0019].

A review of the cited passages reveals that these claims do not anticipate the presently claimed invention. Claim 8, while mentioning Nelumbinis Semen, is dependent on Claim 7, which in turn is dependent on Claim 6, which in turn is dependent on Claim 1. Claim 8, therefore is directed to a root extract of balloon-flower, administered to a mammal in a composition and further comprising a Nelumbinis Semen or an extract thereof.

Claims 12-14 are dependent on Claim 9. Claim 12 is therefore directed to the use of a root extract of balloon-flower wherein the extract is a water extract or an organic solvent extract. Claim 13 is also dependent of Claim 12, and is therefore directed to the use of a root extract of balloon-flower wherein the water extract is prepared by adding water and filtering. Claim 14 is therefore directed to the use of a root extract of balloon-flower wherein the extract is administered to a mammal in a composition. Thus, Nelumbinis Semen is not contemplated in Claim 12, 13 or 14.

Similarly, paragraph [0019] is concerned with a procedure to prepare a balloon-flower root extract and does not mention Nelumbinis Semen.

In contrast, amended claim 1 is directed to a Nelumbinis Semen extract having antidepressive activity, which is prepared by extracting Nelumbinis Semen with water at 80-100°C for 1-3 hours. Such an extract is not taught by Kim, et al., which is concerned with extracts of balloon-flower root, and mixtures of this extract with other herbs.

Kim, et al., not teaching all the elements of Claim 1, cannot anticipate Claim 1 or any claim dependent therefrom.

Based on the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

The Rejection under 35 U.S.C. § 102/103(a)

The Examiner has rejected Claims 1-12 under under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a), as being obvious over Kim, et al., WO 02/102397 (US 2004/0185128 A1 as translation). The Examiner bears the burden of establishing a *prima facie* case of obviousness (Section 103). In determining obviousness, one must focus on Applicant's invention as a whole. *Symbol Technologies Inc. v. Opticon Inc.*, 19 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1991).

The Office action states that the reference discloses an extract which appears to be identical to the presently claimed extract and that the claimed extract appears to be anticipated by the reference. Applicant respectfully traverses this rejection.

As explained in detail above, Kim, et al., being concerned with root extracts of balloon-flower, does not teach all the elements of Claim 1, namely a *Nelumbinis Semen* extract having antidepressive activity, which is prepared by extracting *Nelumbinis Semen* with water at 80-100°C for 1-3 hours.

The Office action further states that even if the reference extract and the claimed extract are not the same, the reference extract would render the claimed extract obvious to one of ordinary skill in the art at the time the claimed invention “in view of the clearly close relationship between the extracts as evidenced by their shared pharmaceutical characteristics.”

As an initial matter, Applicant notes that “[r]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____, 82 USPQ2d 1385, 1396, quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). No reasoning has been provided in the present obviousness rejection, only the conclusory statement that there is a “close relationship” between the extracts because of “shared pharmaceutical characteristics.” Applicant therefore submits that a *prima facie* case of obviousness has not been made with respect to the rejected claims and requests reconsideration on this basis.

Furthermore, Kim, et al., neither teaches nor suggests substituting *Nelumbinis Semen* for the root of balloon-flower. At most, Kim, et al., teaches that *Nelumbinis Semen* may be combined with an extract of the root of balloon-flower.

Regarding the pharmaceutical characteristics of the claimed extract and the prior art extract, Applicant points out that a *Nelumbinis Semen* extract having antidepressive activity is the present invention. Obviousness must be assessed “at the time the invention was made.” *In re Dembiczak*, 175 F.3d 994, 998, 50 USPQ2d 1614, 1616 (Fed. Cir. 1999). Reference to the present invention in making an obviousness rejection represents the use of improper hindsight. The Office action contains no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of the present invention (i.e., a *Nelumbinis Semen* extract having antidepressive activity) to modify the teachings of Kim, et al., in the manner claimed.

In view of the foregoing, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102/103(a) is respectfully requested.

The Double Patenting Rejection

The Examiner has provisionally rejected Claims 1-12 as being unpatentable over Claims 1-5 of copending application no. 11/570,331. An obviousness-type double patenting rejection is appropriate when a claim merely defines an obvious variation of an invention claimed in a patent. M.P.E.P. § 804(II)(B)(1). A double-patenting rejection must rely on a comparison with the claims in an issued or to be issued patent. M.P.E.P. § 804(III).

The rejection reasons that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are directed to an Nelumbinis semen extract with hot water.

Applicant submits that claim 1, as amended, is patentably distinct from the claims of copending application no. 11/570,331. Claim 1 now recites that the extract is prepared by extracting Nelumbinis Semen with water at 80-100°C for 1-3 hours. Applicant submits that this extraction method is more than an obvious variation over a hot water extraction.

Reconsideration and withdrawal of the double-patenting rejection is therefore respectfully requested.

Provisional Obviousness Rejection

Claims 1-12 have been provisionally rejected under 35 U.S.C. § 103(a) as being obvious over copending application no. 11/570,331, which has common inventors with the instant application and has an earlier effective filing date.

No reasoning for the conclusion of obviousness has been provided and therefore a *prima facie* case of obviousness has not been made. Without a description of the rejection, Applicant cannot reply.

Furthermore, and more importantly, Applicant submits the rejection is improper. Since the copending application no. 11/570,331 resulted from an international application meeting the following three conditions:

- (1) an international filing date on or after November 29, 2000;
- (2) designated the United States; and
- (3) published under PCT Article 21(2) in English,

the international filing date of copending application no. 11/570,331 is a U.S. filing date for prior art purposes under 35 U.S.C. 102(e). The 35 U.S.C. 102(e) date of the reference is therefore June 9, 2005, whereas the international filing date of the present application is March 31, 2005. A provisional rejection obviousness rejection under Section 103 using prior art under Section

102(e) should be made in the later filed application. (See M.P.E.P. § 706.02(k)). Since copending application no. 11/570,331 is the later filed application, the rejection, if appropriate, should be made in that application.

Based on the foregoing, reconsideration and withdrawal of the provisional rejection under 35 U.S.C. § 103(a) is respectfully requested.

Closing Remarks

Applicant believes that the pending claims are in condition for allowance. If it would be helpful to obtain favorable consideration of this case, the Examiner is encouraged to call and discuss this case with the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-1970, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-1970.

Respectfully submitted,

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